

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1032V

Filed: April 5, 2022

* * * * *	*	
TASHA LEE, <i>as mother and natural</i>	*	PUBLISHED
<i>guardian of minor A.B., and JOSE</i>	*	
BOTELLO, <i>as father and natural</i>	*	
<i>guardian of minor A.B.,</i>	*	Findings of Fact; Onset; Hepatitis A
	*	Vaccine; Guillain-Barre Syndrome
Petitioners,	*	("GBS").
v.	*	
	*	
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* * * * *	*	

Jeffrey Pop, Esq., Jeffrey S. Pop & Associates, Beverly Hills, CA, for petitioner.
Jennifer Shah, Esq., U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ONSET¹

Roth, Special Master:

On July 31, 2017, Tasha Lee ("Ms. Lee") and Jose Botello ("Mr. Botello") ("petitioners") filed a petition pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.*² ("Vaccine Act" or "the Program") on behalf of their child, A.B. Petitioners allege that A.B. developed Guillain-Barre Syndrome ("GBS") as a result of the hepatitis A vaccination she received on May 3, 2016. Petition at 1, ECF No. 1.

¹ This Ruling has been designated "to be published," which means I am directing it to be posted on the Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). **This means the Ruling will be available to anyone with access to the internet.** However, the parties may object to the Ruling's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public. *Id.*

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Procedural History

The matter was assigned to me on August 1, 2017. ECF No. 1; ECF No. 4. Petitioners filed Ms. Lee's declaration, A.B.'s medical records, and a Statement of Completion on September 29, 2017. Petitioners' Exhibits ("Pet. Ex.") 1-9, ECF No. 7; Statement of Completion, ECF No. 8.

Respondent filed his Rule 4(c) Report ("Resp. Rpt.") on January 3, 2018, recommending against compensation in this matter, submitting that "the onset of AB's condition was within a day of vaccination." In the context of flu vaccine, onset of GBS within a day is understood to be too short a timeframe to support vaccine causation, and this was a hepatitis A vaccine. ECF No. 11; Resp. Rpt. at 4.

Petitioners filed an expert report, CV, and supporting medical literature from Dr. Steinman who opined, "The onset of GBS within 24 hours of the second hepatitis A immunization in A.B. is consistent with the velocity of a recall response." Pet. Ex. 10 at 17. Pet. Ex. 10-19, ECF No. 15; Pet. Ex. 20-29, ECF No. 16; Pet. Ex. 30-38, ECF No. 17.

On August 31, 2018, respondent filed an expert report, CV, and supporting medical literature from Dr. Kruer. Resp. Ex. A, Tabs 1-9, ECF No. 21; Resp. Ex. A, Tabs 10-15, Resp. Ex. B, ECF No. 22. Dr. Kruer wrote that less than 24 hours after receiving a hepatitis A vaccine at around 11:15 am, A.B. "could no longer stand or walk." Resp. Ex. A at 1. Dr. Kruer disagreed with Dr. Steinman that an immunologic response could result in GBS within 24 hours of vaccination. *Id.* at 5-6.

A status conference was held on October 15, 2018 at which time the onset issue was discussed. Also discussed were the various dates of onset that petitioner Lee reported to medical providers following the May 3, 2016 hepatitis vaccination. Scheduling Order at 1, ECF No. 23. Some examples included A.B.'s receipt of the hepatitis A vaccine at 11:00 am on May 3, 2016 with onset of pain and weakness that evening; and the onset of weakness beginning the morning of May 4, 2016. *Id.*, citing Pet. Ex. 4 at 44; Pet. Ex. 5 at 13, 35. Additional medical records noted to be outstanding were ordered at that time. *Id.* at 2.

Following several requests for authority to issue subpoenas, which were granted, petitioners filed the outstanding medical records and a complete immunization record on March 29, 2019. *See* ECF No. 25-30; Pet. Ex. 39-42, ECF No. 31. Petitioners were Ordered to file an expert report from Dr. Steinman which relied solely on the contemporaneous medical records and not the facts regarding onset as detailed in the declarations of petitioners. Scheduling Order at 1, ECF No. 35. A deadline was also set for respondent to file a responsive report from Dr. Kruer. *Id.*

On August 26, 2019, petitioners filed a second report from Dr. Steinman in which he concluded, "at some time during those 25-26 hours [between A.B.'s vaccination at 11:15 am on May 3, 2016 and presentation to the emergency room at 1:32 pm on May 4, 2016], the onset of A.B.'s GBS began." Pet. Ex. 43 at 1. Dr. Steinman maintained his opinion that "medical literature supports an onset of GBS within 24 hours due to a recall response." *Id.*

Respondent filed a responsive report from Dr. Kruer on October 18, 2019 in which Dr. Kruer opined that neither the additional medical records nor Dr. Steinman's second report changed his opinion "that evidence that AB's (sic) GBS was related to vaccination is lacking." Resp. Ex. C at 1; ECF No. 37.

A Rule 5 status conference was held on January 22, 2020. Petitioners' counsel agreed an onset hearing was necessary "in order for A.B.'s mother to explain the various timings of onset she reported to A.B.'s treating physicians." Scheduling Order at 2, ECF No. 38. A joint status report with potential hearing dates was filed on March 9, 2020. ECF No. 39.

An onset hearing was scheduled for August 11, 2020. ECF No. 40. Both English and Spanish versions of Mr. Botello's affidavit were filed on July 1, 2020. Pet. Ex. 46-47, ECF No. 41.

The onset hearing was held on August 11, 2020 via video conference. Both petitioners testified and a Spanish interpreter was utilized for petitioner Botello's testimony.

After the hearing, petitioners were asked to submit a settlement demand to respondent and did so on August 27, 2020. ECF No. 48. On October 13, 2020, respondent filed a status report declining to entertain settlement negotiations based on the record at that time. ECF No. 49.

This matter is now ripe for ruling.

II. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claims by a preponderance of the evidence. § 13(a)(1). A petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for making determinations in Vaccine Program cases regarding factual issues, such as the timing of onset of petitioner's alleged injury, begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are presumed to be accurate and "complete", such that they present all relevant information on a patient's health problems. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in an accurate manner, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013), vacated on other grounds, *Sanchez by & through Sanchez v. Sec'y of Health & Human Servs.*, No. 2019-1753, 2020 WL 1685554 (Fed. Cir. Apr. 7, 2020), review denied, *Sanchez by & through Sanchez v. Sec'y of Health & Hum. Servs.*, 152 Fed. Cl. 782 (2021); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F. 2d. 1525 (Fed. Cir. 1993) ("[i]t strains

reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred"). In making contemporaneous reports, "accuracy has an extra premium" given that the "proper treatment hang[s] in the balance." *Id.* A patient's motivation for providing an accurate recount of symptoms is more immediate, as opposed to testimony offered after the events in question, which is considered inherently less reliable. *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993); see *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948)). Contemporaneous medical records that are clear, consistent, and complete warrant substantial weight "as trustworthy evidence." *Cucuras*, 993 F.2d at 1528. Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Id.*

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as in cases where records are deemed to be incomplete or inaccurate. See *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 775, 779 (2006) ("[L]ike any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking."). The Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be given. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is used to overcome the presumption of accuracy given to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (quoting *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998)); see, e.g., *Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs.*, No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). Moreover, despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. *Vallenizuela v. Sec'y of Health & Human Servs.*, No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); see also *Eng v. Sec'y of Health & Human Servs.*, No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"). In short, "the record as a whole" must be considered. § 13(a).

III. The Factual Evidence

A.B. received the allegedly causal hepatitis A vaccine at approximately 11:15 am on May 3, 2016. Pet. Ex. 3 at 12. She was presented to the emergency room at Odessa Medical Center at approximately 11:00 am on May 4, 2016, though she was not examined until around 1:00 pm. Tr. 24-25; Pet. Ex. 4 at 41-42. Petitioner Lee provided A.B.'s history and communicated with all medical providers. Tr. 12; 25. The medical records demonstrate that petitioner Lee reported various dates and times of onset of A.B.'s leg weakness that was ultimately diagnosed as GBS to several nurses and physicians at various medical facilities. Those reports included onset of leg weakness the evening of May 3, 2016, 7 to 10 hours after vaccination, and onset of leg weakness the following morning, May 4, 2016, when A.B. awoke between 8:00 and 9:00 am. Regardless, A.B.'s onset of bilateral leg weakness occurred within 21 hours after vaccination. The only issue to be determined in this Ruling is the onset of A.B.'s leg weakness following the hepatitis A vaccination of May 3, 2016.

In analyzing onset in this case, the contemporaneous medical records are the first consideration, which if clear, consistent, and complete, warrant substantial weight "as trustworthy evidence." *Cucuras*, 993 F.2d at 1528. The second consideration is the declarations and testimony provided by the petitioners to the court. *Cucuras*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d. 1525 (Fed. Cir. 1993).

A. The Medical Records

The parties agree that A.B.'s medical history is "non-contributory to petitioners' current claim, and she received her Hep A vaccination at a routine well child check that began at 11:15 a.m. on May 3, 2016." Resp. Rpt. at 2; Pet. Ex. 3 at 11-12.

A.B. was born on July 9, 2013. She received all her vaccines without event. *See* Pet. Ex. 39; Pet. Ex. 40; Pet. Ex. 4; Pet. Ex. 42.

On May 3, 2016, A.B. was presented for a routine check-up and was determined to be a well child. At approximately 11:15 a.m., she was given her second hepatitis A vaccination. Pet. Ex. 3 at 11-12; Pet. Ex. 2 at 1; Pet. Ex. 41 at 16; Pet. Ex. 42.

On May 4, 2016, A.B. was presented to the emergency room at Odessa Regional Medical Center ("Odessa") with her mother reporting that A.B. will not stand or walk, she received shots yesterday, and had a "fall a few days ago" but was evaluated by the doctor yesterday. Pet. Ex. 4 at 41. The record documented loss of strength to lower extremities bilaterally since this morning followed by, "Onset: The symptoms/episode began/occurred yesterday and became worse today." Pet. Ex. 4 at 44; Pet. Ex. 40 at 32. It is further noted that the symptoms were aggravated by weight bearing, alleviated by staying still, and that A.B. was "Seen by PMD yesterday for immunization; mother acknowledges fall 2 days ago; mother also acknowledges child unable to make it to the bathroom so she's wearing a diaper." Pet. Ex. 4 at 44; Pet. Ex. 40 at 32.³ The initial impression at Odessa was paresthesia (neuropathy) ascending to lower extremities bilaterally. Pet. Ex. 4 at 44; Pet. Ex. 40 at 43. Bloodwork, urinalysis, and an MRI of the lumbar spine were ordered. All testing

³ In the medical record, this is written in all capital letters.

was negative, and A.B. was transported by ambulance to Covenant Medical Center (“Covenant”) on May 4, 2016 for a higher level of care. Pet. Ex. 4 at 39-40; Pet. Ex. 5 at 6.

The Covenant Emergency Department Report documented a 2 ½ year old who was transferred from Odessa due to an unwillingness to carry weight on her lower extremities: “Mother states the child received routine immunization yesterday at pediatrician’s office and woke up today unwilling to put any weight on her lower extremities.” Pet. Ex. 5 at 6.⁴ The history of present illness section of the Emergency Department’s pediatric intake assessment included “1) patient given Hep a shot on 5/3 1100. Strted (sic) c/o pin (sic) and weakness around 1 2) 5/4 this morning lethargic and not able to stand.” *Id.* at 13. The record further stated that, “1) mom reports patient has had weakness in legs since evening of 5/3. Unable t (sic) 2) stand today. Decreased movement. Cap refill is WNL.” *Id.* at 16. That assessment also included a wound summary, which documented a lower midline scrape on A.B.’s back: “Mother reports patient scraped her back yesterday due to leg weakness.” *Id.*

A neurological consultation was conducted by Dr. Vu on May 5, 2016. Dr. Vu noted a 2-year-old who was well until two days ago when she had a hepatitis A vaccine and later complained of pain in her thighs.

The patient had some weakness on Tuesday night, Wednesday was weaker and continued to complain of pain . . . taken to their local emergency room in Odessa . . . she had blood work and lumbosacral MRI that was normal . . . transferred to Covenant . . . they did a lumbar puncture that was normal. The patient has had progressive weakness on Wednesday night and Thursday, she refuses to bear weight. She is generally weak.

Pet. Ex. 5 at 35. Neurological examination showed diffuse weakness in the upper and lower extremities. No reflexes could be obtained, and gait could not be tested. There was truncal weakness and ataxia. *Id.* at 36. The assessment was weakness status post immunization, most likely GBS reaction. *Id.*

An MRI with contrast of the cervical, thoracic, and lumbar spine on May 5, 2016 revealed abnormal enhancement along the nerve roots indicative of an acute inflammatory polyradiculoneuropathy or GBS. Pet. Ex. 5 at 95.

An EMG/NCS study on May 7, 2016 noted that “[o]ne week ago she developed progressive weakness of her legs and arms. She now is quadriplegic with decreased tone.” The study found “electrical evidence of marked demyelinating polyneuropathy consistent with Guillain-Barre syndrome.” Pet. Ex. 8 at 7-8. A.B. was treated with five days of IVIG therapy without complication. Pet. Ex. 5 at 24. She received physical and occupational therapy throughout her hospitalization, with “gradual improvement of strength in [her] lower extremities.” *Id.*

The Covenant discharge summary states A.B. was unable to bear weight since receiving a hepatitis A vaccination. Pet. Ex. 5 at 23. She was diagnosed with GBS following vaccination. *Id.*

⁴ The Covenant records show that A.B. arrived shortly after midnight on May 5, 2016 and the references in the record appear to refer to the events of May 3 and May 4, even though they were documented upon arrival on May 5. Pet. Ex. 5 at 20.

On May 11, 2016, A.B. was transferred to Trustpoint Rehabilitation (“Trustpoint”) for inpatient rehabilitation for “impaired mobility dysfunction” and “impaired activities” secondary to GBS after receiving a hepatitis A vaccination. She received a hepatitis A vaccination on May 3 and has “been unable to bear weight through her legs since then.” Pet. Ex. 6 at 1. A.B. remained at Trustpoint until August 5, 2016. Her discharge summary diagnosis remained GBS, dysphagia, bilateral lower extremity weakness, and truncal ataxia. She made “excellent progress” but continued to require moderate assistance and outpatient therapies. *Id.* at 4.

A.B. was presented to Permian Basin Rehab Center on August 30, 2016 for outpatient services. She was noted to be a 3-year-old with GBS who received a hepatitis A vaccination on May 3, 2016 “and the next day her mother reported that she was unable to move from the neck down.” Pet. Ex. 7 at 1. She was in the hospital for two weeks and then transferred to rehabilitation for three months. *Id.* She was noted to have a 15-month delay in skills on evaluation, requiring outpatient therapy two to three times a week for six months. *Id.* at 3.

The most recent records filed are from 2017. A.B. was still attending physical therapy due to ongoing sequela. *See* Pet. Ex. 8.

The parties do not dispute that A.B. suffered GBS and has ongoing sequela.

B. Declarations of Petitioners

1. Declaration of Petitioner Tasha Lee

Petitioner Lee is A.B.’s mother. Pet. Ex. 1 at 1. A.B. was born on July 9, 2013 and was a healthy child prior to May 3, 2016. *Id.* at 1-2. On the morning of May 3, 2016, petitioner Lee “took A.B. to the pediatrician for her annual checkup.” *Id.* “A.B. was considered to be a well child” and was given a hepatitis A shot. *Id.* at 2.⁵

Petitioner Lee declared, “By the next day, I noticed that A.B. was unable to use her legs.” Pet. Ex. 1 at 2. Petitioner Lee took A.B. to the emergency room “because she could not walk or stand and had pain in her legs.” She was diagnosed with paresthesia ascending in her legs and was transferred to Covenant, where “A.B. was diagnosed with GBS from the Hepatitis A vaccination.” *Id.*

2. Declaration of Petitioner Jose Botello

Petitioner Botello is A.B.’s father. Pet. Ex. 46 at 1. According to petitioner Botello, A.B. was healthy child before receiving her hepatitis A vaccine on May 3. During the “early evening” on May 3, he “noticed that A.B. seemed sluggish” but he was “not concerned.” *Id.* He “became concerned that something was wrong with A.B.” at “8 AM on May 4, 2016,” when “A.B. woke up and told me that she could not walk.” *Id.* at 2. They “waited a couple of hours to see if A.B.’s

⁵ A.B. was referred to as a 2-year-old throughout the medical records but was almost 3 at her “annual examination” on May 3, 2016, as her date of birth is July 9, 2013.

symptoms would pass” before taking A.B. to the hospital “at around 10 AM.” *Id.* They had to wait “a few hours” before seeing a doctor.⁶ *Id.* A.B. was diagnosed with GBS. *Id.*

C. Testimony of Petitioners

Petitioners Botello and Lee were sequestered during each other’s testimony.

1. Testimony of Petitioner Jose Botello

Petitioner Botello testified with the assistance of an interpreter. He is A.B.’s father and has been a construction worker for 27 years. Tr. 6.

Petitioner Botello stated he took A.B. for her check-up on the morning of May 3, 2016 because he did not work that day. Tr. 7. They did her check-up and gave her the hepatitis A vaccination at the end of the visit. Tr. 7, 13. After the check-up, they went to Los Dos Compadres for lunch, A.B. ate well, they went home, and everything was normal. Tr. 8.

Petitioner Botello stated that later that afternoon, A.B. told him that her right leg hurt in the area of the vaccination site. Later that evening, she told him again “that she was hurting where they had applied the vaccine.” He then stated she told him all day she was hurting, but she did not have difficulty walking. Tr. 9.

According to petitioner Botello, A.B. went to bed in his and petitioner Lee’s bed around 9:00 pm. When he awoke the next morning between 8:00 and 8:30, A.B. was sitting in the bed and could not walk. When he stood her up on the bed, she fell over. Tr. 9-10. He took A.B. into the living room, put her on the sofa, and massaged her legs while petitioner Lee made breakfast. A.B. was unable to walk and couldn’t move her legs. Tr. 10-11. They took A.B. to Odessa Regional Medical Center around 11:00 am. Tr. 11. Petitioner Lee spoke to the doctors and then told him what was going on. Tr. 12. A.B. was examined and they were told she was going to be transferred to Lubbock. Tr. 12.

Petitioner Botello did not know if A.B. had fallen the day before the May 3 pediatric visit because he was at work, but he did not think so. Tr. 13.

According to Petitioner Botello, A.B. is doing well now. Tr. 12.⁷

2. Testimony of Petitioner Tasha Lee

Petitioner Lee was not employed at the time of the hearing. Tr. 16. She has five children. Tr. 17.

According to petitioner Lee, A.B. was a healthy child prior to her GBS diagnosis. Tr. 17. A.B. had a check-up with the pediatrician at around 11:00 am on May 3, 2016, was “perfectly healthy”, and was given the hepatitis A vaccination in her right thigh. Tr. 18-20; Pet. Ex. 3 at 11-

⁶ The hospital record documents an arrival time of 13:32. Pet. Ex. 4 at 41-42.

⁷ The Spanish interpreter was released at the end of Petitioner Botello’s testimony. Tr. 15.

12. They went to lunch at Dos Compadres afterward, and. A.B. was “perfectly normal” and ate and drank like she usually would. Tr. 20. They went home after lunch and A.B. was fine the rest of the day. At around 9:00 pm that evening, A.B. complained of pain in her right thigh where the vaccination was given. Tr. 21, 39-40. She kept saying that it hurt and would put her hand where the Band-Aid was. Tr. 38. Petitioner Lee stated she did not look at the area that A.B. pointed to, but then stated she did look at A.B.’s leg to see if it was swollen or red. She massaged it and felt the area to see if there was a bump or if it was bigger than normal, but it was not. Tr. 38-39. A.B. went to bed around 10:00 and slept in petitioners’ bed between petitioners Lee and Botello. Tr. 21.

Petitioner Lee initially stated that A.B. woke twice cranky and crying during that night and that petitioner Lee had to cuddle and console her. She stated she was not concerned because being cranky and having pain after vaccinations was normal. Tr. 22. However, she later admitted A.B. was still not sleeping through the night and would usually wake twice during the night. Tr. 22-23, 39-40. Petitioner Lee further admitted that when A.B. awoke during that night, she awoke with her “usual nightly crying,” was not in pain, and did not have a fever. Petitioner Lee rocked her back to sleep and she slept the rest of the night. Tr. 39.

Petitioner Lee stated that A.B. awoke around 8:30 the next morning, crying a bit more and “[S]he just laid there still.” She would usually get up happy. Tr. 23-24. “She had no mobility and was just weak.” Tr. 24. Later, petitioner Lee stated that when A.B. woke around 8:00 or 9:00 am on May 4 she was unable to stand. The last time A.B. stood was at 9:00 or 10:00 pm the night of May 3. Tr. 39-40. According to petitioner Lee, petitioner Botello took A.B. into the living room. They tried to feed her, but she would not eat, so they took her to Odessa around 11:00 am and waited about two hours to be seen. Tr. 24. When A.B. was finally seen, petitioner Lee told them A.B. had a vaccine the day before and “I told them that her symptoms started in the morning. That she had pain the night prior, but her symptoms is when I noticed was in the morning”. Tr. 24-25.

Petitioner Lee was then questioned about the various inconsistencies in her reports to various medical professionals. Petitioner Lee was asked about the nurse’s record at Odessa that reads “She will not stand or walk. Mother reports patient getting her shots yesterday. Mother also reports a fall a few days ago, but she was evaluated by her doctor yesterday.” Tr. 25-26; Pet. Ex. 4 at 41. Petitioner Lee stated she told the nurse about the shot the day before and that A.B. would not stand or walk but did not recall a fall a few days prior. Tr. 26-27. However, she added, A.B. was a normal child who would play and trip here and there, but not often. Tr. 37. She further stated if A.B. had fallen and she was concerned, she would have told the pediatrician. Tr. 27.

Petitioner was questioned about the May 4, 2016 physician’s record from Odessa that contains, “Seen by PMD yesterday for immunization. Mother acknowledges fall two days ago. Mother also acknowledges child is unable to make it to the bathroom so she’s wearing a diaper.” Tr. 27-28; Pet. Ex. 4 at 44-46. Petitioner Lee did tell the doctor that A.B. was seen for immunization yesterday and could not make it to the bathroom so she was wearing a diaper but added that A.B. was not fully potty trained at that time. She did not recall telling the doctor A.B. had fallen but she “may have.” Tr. 28.

When asked about the physician's record noting "Onset. The symptoms episode began/occurred yesterday and became worse today," she stated she was referring to the pain in the right leg beginning yesterday, not the loss of strength to the lower extremities. Tr. 29.

Petitioner Lee was then questioned about the Covenant record, specifically the entry for history of present illness, which reads, "(1) Patient given hep A shot on 5/3, 1100, started C/O pin (sic) and weakness around 1:00 2) 5/4 this morning lethargic and not able to stand" Tr. 29-30; Pet. 5 at 13. Petitioner Lee stated the shot was given on May 3 around 11:00. At 1:00, they were at the restaurant and A.B. was fine. Tr. 30. Petitioner Lee then stated A.B. woke up crying around 1:00 in the morning but went back to sleep and was lethargic and unable to stand the morning of May 4. Tr. 31. She was then asked if A.B. had weakness at 1:00 am when she woke up crying. She stated "No, because she was laying in bed." Tr. 36-37. Following the exchange, petitioner Lee then denied having any idea where the information about 1:00 had come from. Tr. 37.

Petitioner Lee was questioned about the Covenant record which contained, "Mom reports patient has had weakness in legs since evening of 5/3. Unable to stand today, decreased movement." Tr. 31; Pet. Ex. 5 at 16. Petitioner Lee denied telling the doctor that A.B. had "weakness in legs since evening of 5/3 . . . I told them she had pain in her right leg," and the weakness began on the morning of 5/4. Tr. 31. She stated the remainder of the statement "unable to stand today, decreased movement" was accurate. Tr. 32. Petitioner Lee added A.B. complained of pain in her right thigh around 8:00 or 9:00 pm on May 3. Tr. 36.

Petitioner Lee was questioned about the neurology consultation note from May 5, 2016 which states, "This is a two-year-old who was well until two days ago when she had hepatitis A vaccine. The patient later complained of pain in the thighs. The patient has some weakness on Tuesday night; Wednesday was weaker and continued to complain of pain." Tr. 32; Pet Ex. 5 at 35. Petitioner Lee stated the part about "a two-year-old who was well until two days ago when she had a hepatitis A vaccine" was correct. Tr. 32. However, she "specifically let him know it was the right thigh where she received the vaccine" that was painful and never told him A.B. had "weakness Tuesday night; Wednesday weaker." The weakness and no mobility started the next morning. Tr. 32-33.

Finally, petitioner denied the accuracy of the following record, "Patient given hepatitis A shot on 5/3, 1100. Started C/O pin (sic) and weakness around 1800. 5/4, this morning, lethargic and not able to stand." Tr. 33-34; Pet. Ex. 5 at 165. She stated the portion that says A.B. had "weakness around 6:00 (1800) in the evening on May 3rd" was wrong: "She didn't. Her pain started around 9:00, May 3." However, the rest of that entry, "5/4, this morning, lethargic and not able to stand", was correct. Tr. 34.

At the end of her testimony, petitioner summarized, stating A.B. received the vaccination at 11:00 am on May 3, they went to lunch, and A.B. was fine all day. A.B. complained of pain at the vaccination site around 9:00 or 10:00 that evening and would put her hand where the Band-Aid was. Petitioner Lee massaged A.B.'s thigh; it was not red or swollen and there was no bump. A.B. went to sleep in petitioners' bed at about 10:00 pm and woke twice during the night crying, which was usual for her. When she awoke at 8:00 or 9:00 am on May 4, she was unable to stand. The last time petitioner Lee saw A.B. stand was at 9:00 or 10:00 pm the night of May 3. Tr. 38-

40. At Odessa, they were told that A.B. had GBS and she was being transferred to Lubbock, three and a half hours away. Tr. 34-35. A.B. was at Lubbock for about a week while they gave her antibodies, and then she was transferred to Trustpoint for three months. Tr. 35. A.B. is doing better now. Tr. 36.

IV. Discussion and Finding of Onset

A. The medical records and petitioner Lee's testimony support the onset of weakness and pain at the injection site on the evening of May 3, 2016.

The contemporaneous medical records show that petitioner Lee repeatedly reported an onset of pain at the vaccination site and weakness on the evening of May 3, 2016, between 6:00 and 9:00 pm, 7-10 hours after A.B.'s receipt of the hepatitis A vaccination, and that A.B. was unable to stand the next morning when she awoke on May 4 at around 8:00 or 9:00 am. Pet. Ex. 4 at 44; Pet. Ex. 5 at 13, 16, 35, 165; Pet. Ex. 6 at 1. Additionally, upon arrival at Covenant late the night of May 4 or early the morning of May 5, petitioner Lee reported that A.B. "scraped her back yesterday due to leg weakness" when asked about an abrasion on A.B.'s back. Pet. Ex. 5 at 16.⁸

More specifically, petitioner refuted the accuracy of the records as follows: "Onset. The symptoms episode began/occurred yesterday and became worse today," stating the pain in the right leg began yesterday, not the loss of strength to the lower extremities. Tr. 29. The entry stating "Mom reports patient has had weakness in legs since evening of 5/3. Unable to stand today, decreased movement" was inaccurate, except for the portion about the weakness the day of presentation. Tr. 31-32; Pet. Ex. 5 at 16. The neurology consultation note on May 5, 2016 was also inaccurate, "This is a two-year-old who was well until two days ago when she had hepatitis A vaccine. The patient later complained of pain in the thighs. The patient has some weakness on Tuesday night; Wednesday was weaker and continued to complain of pain" Tr. 32; Pet. Ex. 5 at 35. Petitioner Lee stated that the only portion of that records that was correct was, "a two-year-old who was well until two days ago when she received a hepatitis A vaccine." Tr. 32. She stated she never told the neurologist that A.B. had "weakness Tuesday night; Wednesday weaker." The weakness and no mobility started the next morning. Tr. 32-33. Further, the record, "Patient given hepatitis A shot on 5/3, 1100. Started C/O pin (sic) and weakness around 1800. 5/4, this morning, lethargic and not able to stand," was also inaccurate. Tr. 33-34; Pet. Ex. 5 at 165. Petitioner Lee denied A.B. had "weakness around 6:00 in the evening on May 3rd. . . . Her pain started around 9:00, May 3." However, the remainder of the record, "5/4, this morning, lethargic and not able to stand" was correct. Tr. 34.

Succinctly, petitioner Lee agreed only to the accuracy of those portions of the record that documented A.B.'s inability to stand on the morning of May 4, 2016 but denied the accuracy of any portion of the record that documented weakness on the evening of May 3, 2016. Petitioner Lee maintained that she only reported pain at the injection site on the evening of May 3, 2016. Specifically, she stated she told the doctors and nurses at both Odessa and Covenant that A.B. had a vaccination on May 3 with pain at the vaccination site that night. Her loss of strength in the lower extremities was observed in the morning of May 4, 2016. Tr. 24-25, 29, 36-37, 39-40.

⁸ As stated above, the Covenant records show the history taken 0040 on May 5, 2016 referenced A.B. as unable to stand "this morning" 5/4, and petitioner Lee's reference to the scratch sustained yesterday, being May 3, 2016.

B. Petitioner Botello's testimony and declaration do not refute or support the onset of A.B.'s GBS symptoms.

Petitioner Botello testified with the assistance of a Spanish interpreter. The extent to which petitioner Botello understands and speaks English is unclear, but he deferred to petitioner Lee as more informed about A.B.'s medical history, stating she spoke to the doctors and medical personnel and would report back to him. Tr. 12.

In his declaration, petitioner Botello submitted that A.B. received the hepatitis A vaccination around 11:00 am on May 3, 2016, and by "early evening" of May 3, he "noticed that A.B. seemed sluggish" but was "not concerned." Pet. Ex. 46 at 1-2. He "became concerned that something was wrong with A.B." at "8 AM on May 4, 2016, the morning after A.B. got the Hepatitis A shot." *Id.* at 2. According to petitioner Botello, "A.B. woke up and told me that she could not walk," and he "waited a couple of hours to see if A.B.'s symptoms would pass" before they took A.B. to the hospital "at around 10 AM." *Id.*

At hearing, petitioner Botello stated he went with A.B. for her check-up on the morning of May 3, 2016. Tr. 7-8. She received the hepatitis A vaccination at the end of the visit. Tr. 7, 13. After the visit, they went to Los Dos Compadres for lunch, A.B. ate well, they went home, and everything was fine. Tr. 8.

That afternoon, A.B. told petitioner Botello that her right leg hurt where the vaccination was given. Later that evening she told him again "that she was hurting where they had applied the vaccine." He then stated she told him it was hurting all day but did not have difficulty walking. Tr. 9.

According to petitioner Botello, A.B. went to bed in his bed around 9:00, pm and when he awoke the next morning between 8:00 and 8:30, A.B. was sitting up in bed but could not walk. When he stood her up on the bed, she fell over. Tr. 9-10. He took A.B. into the living room, put her on the sofa, and massaged her legs while petitioner Lee made breakfast. A.B. was unable to walk and couldn't move her legs. Tr. 11. They took A.B. to Odessa Regional Medical Center around 11:00 am, A.B. was examined, and they were told she was going to be transferred to Lubbock. Tr. 11-12.

It is unclear what petitioner Botello meant when he stated that A.B. was sluggish the night of May 3, 2016. He recalled A.B. complaining of right leg pain at the injection site all day on May 3, 2016 and made no mention of her waking during the night, but stated she was sitting in bed and unable to stand by 8:00 or 8:30 am the following morning. Therefore, whether A.B. had weakness the evening of May 3, 2016 is neither helped nor hindered by petitioner Botello.

C. The credibility of the witnesses and conclusions on onset of symptoms

As set forth above, determining the onset of A.B.'s bilateral lower extremity weakness later diagnosed as GBS, includes consideration of the contemporaneous medical records first—which, if clear, consistent, and complete, warrant substantial weight "as trustworthy evidence"—and consideration of the declarations and testimony provided by the petitioners to the court second.

Cucuras, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d. 1525; 1528 (Fed. Cir. 1993). This case like *Cucuras*, involves a sick child. Therefore, “[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter’s symptoms.” *Id.* In making contemporaneous reports, “accuracy has an extra premium” given that “proper treatment hang[s] in the balance.” *Id.* A patient’s motivation for providing an accurate recount of symptoms is more immediate as opposed to testimony offered after the events in question, which is considered inherently less reliable. *Reusser v. Sec’y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993); *see Murphy v. Sec’y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir. 1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1948)).

In this case, there is no dispute that A.B. was a healthy child on May 3, 2016 when she received the hepatitis A vaccine. There is no dispute that A.B. was subsequently diagnosed with and treated for GBS. There is no dispute that A.B. continues to suffer from sequela as a result of GBS. The only factual determination to be made in this Ruling is the onset of A.B.’s leg weakness.⁹

The dilemma here, regardless of whether this Ruling places onset on the evening of May 3 around 6:00 pm or at some point thereafter but before 8:00-8:30 am when A.B. awoke on the morning of May 4 unable to stand, is that the onset of GBS is between 7 and 21 hours after receipt of the hepatitis A vaccination.

Petitioner Lee’s testimony several years after the events places onset at the outer limits of that 21-hour period, thus rendering her testimony inconsistent with her reports to medical providers at the time A.B. was presented for care.

After carefully analyzing the medical records, declarations, and testimony of the petitioners, I find that the records consistently, cogently, and clearly reflect that it was reported to various medical personnel at different medical facilities that A.B. received a hepatitis A vaccination at around 11:15 am on May 3, 2016¹⁰ and had onset of leg weakness and pain at the vaccination site on the evening of May 3, 2016 around 6:00 pm or 1800 hours.¹¹ A.B. awoke the next morning sometime between 8:00 and 8:30 am and was unable to bear weight.¹² The onset of weakness on May 3 is further supported by petitioner Lee explaining to medical personnel that the scrape found on A.B.’s back during examination was sustained from a fall due to leg weakness.¹³

Petitioners Lee and Botello are vigilant and dedicated parents who undoubtedly reported her medical history with as much detail and precision as they could on May 4, 2016 and thereafter when presenting her for care. They were for the most part credible witnesses. Therefore, based on the record in its entirety, A.B. was a healthy child who received a hepatitis A vaccination at approximately 11:15 am on May 3, 2016, and suffered from pain at the injection site that day with onset of weakness between 6:00 and 9:00 pm that same evening, 7 to 10 hours after receipt of a hepatitis A vaccine. The weakness caused A.B. to fall, resulting in a scratch on her back. The

⁹ Entitlement to compensation remains disputed by the parties.

¹⁰ Tr. 19; Pet. Ex. 5 at 13, 165; Pet. Ex. 3 at 11-12; Pet. Ex. 41 at 16.

¹¹ Tr. 9, 21, 39-40; Pet. Ex. 5 at 16, 35, 165; Pet. Ex. 4 at 44.

¹² Tr. 9-10, 39-40; Pet. Ex. 5 at 6, 13, 16, 165; Pet. Ex. 1 at 2; Pet. Ex. 46 at 2.

¹³ The documenting of the scrape on A.B.’s back suggests that a body check was performed. No swelling or redness at the injection site was documented. Petitioner Lee explained the scrape on A.B.’s back as the result of a fall due to weakness in her legs on May 3. Pet. Ex. 5 at 16.

following morning, on May 4, 2016, A.B. was unable to stand when she awoke between 8:00 and 8:30 am. Tr. 9, 21, 39-40; Pet. Ex. 5 at 16, 35, 165; Pet. Ex. 4 at 44. She was subsequently diagnosed with GBS and continues to suffer from sequela.

V. Conclusion

Upon detailed review of the record in its entirety, I find that A.B. received a hepatitis A vaccine at approximately 11:15 am on May 3, 2016. She began to suffer from pain at the injection site later that day, with onset of weakness between 6:00 and 9:00 pm on the evening of May 3, 2016 causing a fall that resulted in a scrape on her back. When A.B. awoke the next morning on May 4, 2016, she was unable to stand.

To continue pursuing their claim, petitioners must file an expert report from Dr. Steinman which relies on the facts as found in this Ruling, specifically onset of her pain and leg weakness between 7 to 10 hours after vaccination with hepatitis A. Should petitioners' expert base his opinion on facts not substantiated by this Ruling, the expert's report will be disregarded. *See Burns by Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993).

Accordingly, the following is ORDERED:

By no later than Friday, May 20, 2022, petitioners shall file either an expert report that is based on the onset as found herein, or a status report indicating how they intend to proceed. Petitioners shall provide a copy of this Onset Ruling to their expert witness and their expert shall rely on the timing of onset as I have found it in this Ruling. If petitioners are unable to secure reports from their expert based on the timing of onset as I have found it, they shall file either a motion to dismiss, a joint stipulation for dismissal, or a motion for a ruling on the record, all of which will result in the dismissal of their claim.

IT IS SO ORDERED.

s/Mindy Michaels Roth

Mindy Michaels Roth
Special Master